SECTION 5 - 510(k) Summary - ELITech Clinical Systems AST/GOT 4+1 SL on Vital Scientific Selectra Junior

SEP 20 2010

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is : K093883

Submitter SEPPIM S.A.S.
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Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation November 27th , 2009

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems AST/GOT 4+1 SL**
Common or Usual Name:	AST-Aspartate amino Transferase, **"AST/GOT 4+1 SL"**
Device Class	Class II
Classification name	Aspartate amino transferase (AST/SGOT) Test system (21 CFR.862.1100)
Product code	CIT; NADH oxidation/NAD reduction, Ast/Sgot

INSTRUMENT:

Trade/Proprietary Name:	**Vital Scientific Selectra Junior**
Common or Usual Name:	Clinical analyzer, **"Selectra Junior"**
Device Class:	Class I
Classification Name:	Discrete Photometric Chemistry Analyzer for Clinical Use (21 CFR 862.2160)
Product Code:	JJE

Predicate devices ABX PENTRA AST CP (K060318)
Vitalab Flexor (973628)

Device description The reagent device for this submission is available as kit only. It consists of 2 reagents:
Reagent 1 contains Tris buffer, L-Aspartate; Lactate dehydrogenase (LDH) (microorganisms), Malate dehydrogenase (MDH) (bacterial) and sodium azide.
Reagent 2 contains α-Ketoglutarate, NADH and sodium azide
The Vital Scientific Selectra Junior is a benchtop discrete chemistry photometric analyzer for *in vitro* diagnostic use.

Intended Use The Vital Scientific Selectra Junior Analyzer (also trademarked as the Vital Scientific Flexor Junior Analyzer) is a discrete photometric chemistry analyzer for *in vitro* diagnostic use.

ELITech Clinical Systems AST/GOT 4+1 SL reagent is for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate amino transferase in human serum and plasma on the Vital Scientific Selectra/Flexor Analyzers. Aspartate Amino Transferase (AST) measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Indication(s) for Use ELITech Clinical Systems AST/GOT 4+1 SL is intended to measure the enzyme Aspartate amino transferase (AST) in human serum and plasma. Measurements of aspartate amino transferase levels are used in the treatment of certain types of liver and heart diseases.

Comparison to Predicate device

	ELITech Clinical Systems Device (AST/GOT 4+1 SL)	Predicate device (ABX PENTRA AST CP)
Intended use	ELITech Clinical Systems AST/GOT 4+1 SL reagent is for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate amino transferase in human serum and plasma on the Vital Scientific Selectra/Flexor Analyzers. analyzers for the quantitative *in vitro* diagnostic determination of the enzyme Aspartate amino transferase (AST) in human serum and plasma.	For *in vitro* diagnostic use in the quantitative determination of aspartate aminotransferase (AST) in serum or plasma.
Indication for Use	Measurement of aspartate amino transferase levels aids in the treatment of certain types of liver and heart diseases.	Measurement of aspartate amino transferase levels aids in the treatment of certain types of liver and heart disease.
Assay protocol	Modified IFCC method without pyridoxal -phosphate	Optimized UV test according to IFCC modified method without pyridoxal phosphate.
Composition	Reagent R1 : TRIS pH 7.8, 100 mmol/L; L-Aspartate 330 mmol/L; MDH ≥ 1000 U/L; LDH ≥ 2000 U/L; Sodium azide < 1g/L Reagent R2 : α-Ketoglutarate 78 mmol/L ; NADH 1.1 mmol/L ; Sodium azide < 1g/L	Reagent R1 : TRIS pH 7.8 110 mmol/L; L-Aspartate 340 mmol/L; MDH ≥ 900 U/L; LDH ≥ 900 U/L; Sodium azide < 1g/L Reagent R2 : 2-oxoglutarate 85 mmol/L ; NADH 1.09 mmol/L ; Sodium azide < 1g/L
Appearance of reagents	Liquid form, ready to use	Liquid form, ready to use
Traceability/Standardization	IFCC formulation (Schumann, 2002), manual measurement	IFCC Reference Measurement Procedure (37°C) for ASAT
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin
Reagent storage	Store at 2-8°C and protected from light. The reagents are stable until the expiry date stated on the label	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8°C, and contamination is avoided.
Expected values	Serum, Plasma (37°C) :< 40 U/L	Women < 31 U/L Men < 35 U/L } 37°C
Instrument	Vital Scientific Selectra Junior Analyzer (also trademarked as the Flexor Junior Analyzer)	ABX PENTRA 400
Measuring range	10 to 250 U/L	3.70 U/L to 600 U/L

		Automatic post-dilution:1800 U/L
Precision	**Within run** Level 21.2 U/L CV=2.3% Level 46.4 U/L CV=0.8% Level 203.4 U/L CV=0.5% **Total** Level 21.2 U/L CV=3.8% Level 46.4 U/L CV=1.2% Level 203.4 U/L CV=2.7%	**Within run** Level 42 U/L CV=2.7% Level 123 U/L CV=1.4% Level 22 U/L CV=2.3% Level 38 U/L CV=2.0% Level 145 U/L CV=1.1% **Total** Level 42 U/L CV=3.1% Level 126 U/L CV=2.5% Level 43 U/L CV=3.6% Level 348 U/L CV=5.0%
Method comparison	y=1.016x – 1.86 U/L R^2= 0.9998 range: 9.5 to 234.4 U/L	y=0.99x +1.01 U/L r^2= 0.9966 range: 3.70 to 671.80 U/L
Calibration Frequency	28 days	8 days
On board stability	refrigerated area : 28 days	refrigerated area: 55 days

Conclusion

The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELICAL 2

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: K093883

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Date of Preparation November 27th, 2009

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems ELICAL 2**
Common or Usual Name:	Calibrator, secondary, "**ELICAL 2**"
Device Class	Class II
Classification name	Calibrator (21 CFR 862.1150)
Product code	JIT- Calibrator, secondary

Predicate device Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

Device description ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use ELITech Clinical Systems ELICAL 2 is a single parameter calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s.)
Intended use	ELITech Clinical Systems ELICAL 2 is a single parameter calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.	For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open one bottle, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : - 8 hours between 15-25 °C. - 2 days between 2-8 °C. - 4 weeks between -25 and -15 °C (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 8 hours at 15-25 °C. - 2 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once) *Exception for bilirubin total & direct as noted in package insert

Conclusion	The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELITROL I and ELITROL II

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: K093883

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Date of Preparation November 27th, 2009

Device names

CONTROLS:

Trade/proprietary Name:	**ELITech Clinical Systems ELITROL I and ELITROL II**
Common or Usual Name:	Single analyte, Assayed, **"ELITROL I"- "ELITROL II"**
Device Class	Class I
Classification name	Quality control material (assayed and unassayed). (21 CFR 862.1660)
Product code	JJX- Single (specified) analyte control, (assayed)

Predicate device

Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

Device description

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.
Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use

ELITech Clinical Systems ELITROL I is a single parameter control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a single parameter control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical

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Systems methods on the Vital Scientific Selectra Junior analyzer and the Vital Scientific Flexor Junior analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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SEP 20 2010

Re: k093883
Trade Name: AST/GOT 4+1 SL
Regulation Number: 21 CFR §862.1100
Regulation Name: Aspartate aminotransferase (AST/SGOT) Test System
Regulatory Class: Class II
Product Codes: CIT, JJX, JIT, and JJE
Dated: August 30, 2010
Received: September 1, 2010

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K093883

Indications for Use Form

SEP 20 2010

510(k) Number (if known): _K093883_____

Device Name: _Vital Scientific Selectra Junior Analyzer (also trademarked as the Flexor Junior Analyzer) AST/GOT 4+1 SL___

Indications for Use:

The Vital Scientific Selectra Junior Analyzer (also trademarked as the Vital Scientific Flexor Junior Analyzer) is a discrete photometric chemistry analyzer for *in vitro* diagnostic use.

ELITech Clinical Systems AST/GOT 4+1 SL reagent is for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate amino transferase in human serum and plasma on the Vital Scientific Selectra/Flexor Analyzers. Aspartate Amino Transferase (AST) measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093883

Indications for Use Form

K093883
SEP 20 2010

510(k) Number (if known): _K093883_____

Device Name: _____ELICAL 2_____

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a single parameter calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093883

Indications for Use Form

K093883

510(k) Number (if known): __K093883_____

Device Name: _____ELITROL I and ELITROL II_____

Indications for Use:

ELITech Clinical Systems ELITROL I is a single parameter control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a single parameter control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior analyzer and the Vital Scientific Flexor Junior analyzers.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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